

Remarks/Arguments:

Applicants wish to thank the examiner for the careful attention given the Rules in making the instant action non-final.

Claims 1, 2, and 6-10, currently amended, and claim 11, previously presented, are pending.

Claims 3-5, 12, and 13 are canceled, without prejudice or disclaimer.

Claim 6 is withdrawn, pursuant to restriction.

Examination was limited to SEQ ID NOS: 7, 9, and 14 pursuant to election/restriction, made final in the Office Action. Reconsideration of the final election/restriction requirement is requested, as set forth below.

Claims 1-9 are amended by changing the "medicament for treating neoplasms comprising a combination of" to a "composition comprising a physiologically acceptable combination of."

Claim 8 is amended to correct a misspelling.

Claim 10 and claim 11 (being dependent on claim 10) are amended by adding the proviso "excluding SEQ ID NOS: 1, 4, 5, 9, 11-13, 15-18, 20, 22, 23, and 25-27." The proviso is added in connection with the §101 rejection, discussed below.

The objection to claim 8 is overcome by amending the claim to correctly spell "interleukins."

Claims 1, 2, and 7-9 were rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the written description requirement. Reconsideration is requested.

First of all, the rejection is not for the same reasons set forth in the previous Office Action, as maintained in the statement of rejection. According to the reasoning set forth in the prior

rejection, "the disclosure fails to provide a representative number of species to describe the various genera claimed" (Office Action mailed April 4, 2005, page 6, last three lines). This reasoning is not used as the basis of the present rejection (nor is it repeated).

According to the present statement of rejection the written description requirement is not satisfied because the rejected claims allegedly encompass

treatment effects, as embraced by the claimed term "medicament."

In other words, the rejection relies on the term "medicament" appearing in the claims, otherwise, the "treatment effects"—the alleged lack of which being the missing written description necessary to satisfy §112, ¶1—would not be an inherent feature of the claims, according to the statement of rejection.

Contrary to the rejected claims, the present claims do not recite the term "medicament" and, so, do not inherently embrace the "treatment effects," inherently embraced by the term "medicament." Since the "treatment effects" are not embraced by the present claims, the rejection is no longer supported, i.e., the statement of rejection fails to identify any subject matter presently claimed for which the specification fails to satisfy the written description requirement of §112, ¶1. Withdrawal of the rejection appears to be in order.

Claims 1, 2, and 7-9 were rejected under 35 USC 112, first paragraph, for allegedly lacking enablement. Reconsideration is requested.

First of all, with all due respect, the statement of rejection does not answer the arguments traversing the rejection set forth in applicant's amendment filed October 4, 2005. The statement of

rejection mistook the arguments traversing the written description rejection for the arguments traversing the enablement rejection, repeated as follows.

According to the statement of rejection, the rejection is based, *i.a.*, on the allegation "Applicants have not provided guidance in the specification toward a method of treating *any* neoplasm" (Office Action, page 9, *emphasis added*). In other words, satisfaction of enablement under §112, ¶1, (according to the statement of rejection) that the present specification must enable the treatment of *any* neoplasm. In this respect, the statement of rejection is mistaken.

Enablement under §112, ¶1, is satisfied for using the claimed invention when the "claimed invention meets at least one . . . objective" stated in the specification. *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1094, 1100 (Fed. Cir. 1991). "An invention . . . need only be useful to some extent and in certain applications." *Id.* Total incapacity, i.e., incapacity with respect to all uses of the invention described in the specification, is necessary to demonstrate lack of enablement with respect to the invention claimed. *Tol-O-Matic Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H.*, 20 USPQ2d 1332, 1338 (Fed. Cir. 1991).

The statement of rejection admits that enablement is satisfied for at least one stated objective—"for treating a brain neoplasia" (Office Action, page 7). Accordingly, the statement of rejection implicitly acknowledges that enablement is satisfied for the presently claimed invention. *Carl Zeiss Stiftung, supra*.

Furthermore, according to the statement of rejection (Office Action, page 4, last incomplete ¶), the specification is "enabling for in vitro inhibition of TGF-β." Thus, the statement of rejection admits that enablement is satisfied for at least one more stated objective (besides "for treating a brain neoplasia")—in vitro inhibition of TGF-β. Accordingly, the statement of rejection

(again) implicitly acknowledges that enablement is satisfied for the presently claimed invention.

Carl Zeiss Stiftung, supra.

Further, still, it must be remembered that the present claims are not drawn to a medicament bu, rather, to a "composition." Any reasoning based on the term "medicament" appearing in the claims is, accordingly, no longer relevant. (Office Action, page 7).

For the foregoing reasons, withdrawal of the rejection under §112, ¶1, for alleged lack of enablement, appears to be in order.

Claims 1, 2, 7, 8, 10, and 11 were provisionally rejected under 35 USC 101 as allegedly claiming the same invention as claims 12-15 in US10/984,919. Reconsideration of the rejection is requested for the reasons of record.

The rejection is provisional. It only applies if and when claims 12-15—in the form relied on to support the rejection—are patented. Accordingly, the rejection is premature, since the claims relied on might never issue in a patent. Until the rejection is no longer provisional, no further reply is necessary.

Claims 1, 2, 7, 8, 10, and 11 were rejected under 35 USC 102(b) as being allegedly anticipated by WO94/25588 (Schlingensiepen). Reconsideration of the rejection is requested.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The "absence" from a prior art reference of a single claim limitation "negates anticipation." *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81, 84 (Fed.

Cir. 1986). A reference that discloses "substantially the same invention" is not an anticipation. *Jamesbury Corp.* To anticipate the claim, each claim limitation must "*identically* appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997) (*emphasis added*). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

Schlingensiepen does describe an antisense oligonucleotide corresponding to SEQ ID NO: 9. On the other hand, neither the Abstract, nor Figure 8, nor any of pages 14, 22, and 23 (nor, apparently, the entire disclosure) of the reference describes the component (limitation) "stimulator positively effecting an immune response" of the rejected "medicament" claims (and the present "composition claims"), allegations to the contrary in the statement of rejection, notwithstanding. As the reference fails to meet all limitations of the rejected (and present) claims.

Accordingly, the "absence" from Schlingensiepen of one of the limitations on the rejected (and present) claims "negates anticipation" by the reference. *Kolster Speedsteel A B*, 230 USPQ at 84. Withdrawal of the rejection under §102(b) appears to be in order.

Claims 10 and 11 were rejected under 35 USC 101 for allegedly claiming the same invention as claims 1-3 of US6455689. Reconsideration is requested.

In view of the proviso—"excluding SEQ ID NOS: 1, 4, 5, 9, 11 to 13, 15-18, 20, 22, 23, 25, 26, and 27"—limiting claims 10 and 11 (currently amended), none of the remaining recited sequences—non-excluded from "SEQ ID NOS: 1-213"—meets any of the sequences recited in each

of claims 1-3 in US6455689. Accordingly, the §101 rejection is overcome and, so, withdrawal of the rejection appears to be in order.

Request to Reconsider Final Restriction/Election Requirement

Moreover, with all due respect, even if MPEP 2434 were not violated, the restriction/election is, still, improper for requiring election of, and limiting examination to, only three (3) nucleotide sequences—contrary to the requirements of MPEP 803.04. In accordance with MPEP 803.04 ("Nucleotide Sequences") (emphasis added),

"nucleotide sequences" . . . normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. . . . Nevertheless, . . . without creating an undue burden on the Office, the Director has decided sua sponte to . . . permit a reasonable number of such nucleotide sequences to be claimed in a single application. . . . [N]ormally ten sequences constitute a reasonable number for examination purposes. . . . Applications claiming more than ten . . . will be subject to a restriction requirement. Only the ten nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined.

Contrary to the requirements of MPEP 803.04, the restriction/election incorrectly (1) required selection of only three nucleotide sequences, rather than the requisite "ten nucleotide sequences," and (2) restricted examination to the three elected nucleotide sequences, rather than "the ten nucleotide sequences . . . and any other claimed sequences which are patentably indistinct therefrom," as required.

The restriction/election violates the requirements of MPEP 2434, as pointed out in applicants' traverse, accompanying their election. Compliance with MPEP 2434 requires that SEQ ID NOS:

1-32 and 58-67—less those sequences expressly excluded by the claims—must be examined together, since they correspond to a single gene encoding the single protein TGF- β .

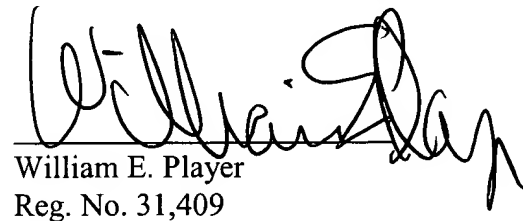
For the foregoing reasons, withdrawal of the final restriction/election requirement appears to be in order. Moreover, in the event a new (replacement) restriction/election requirement is made, it should be in compliance with MPEP 803.04—by providing for election of at least "ten nucleotide sequences" and by examining followed "the ten nucleotide sequences . . . and any other claimed sequences which are patentably indistinct therefrom."

Favorable action is requested.

Respectfully submitted,

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